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AND SRI LANKA

September 24, 2019

VIA ECF

The Honorable Robert Kugler
Senior United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 4D
Camden, NJ 08101

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

**Re: In re Valsartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS**

Dear Judge Kugler and Judge Schneider:

This letter is to provide Defendants' position with respect to the topics on the agenda for the Case Management Conference with the Court on September 25.

1. Plaintiff Fact Sheets

No outstanding disputes remain with respect to the Personal Injury Plaintiff's Fact Sheet. Defendants sent the finalized draft to Plaintiffs for review and confirmation on September 12,

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2019. Defendants will prepare an order for the Court to review and sign approving this Fact Sheet and laying out the show cause process for the parties to address deficiencies in the fact sheets as they arise.

Defendants sent drafts of the Medical Monitoring and Economic Loss Class Representative Plaintiff's Fact Sheets to Plaintiffs for review on September 17, 2019. Both of these fact sheets are comprised almost entirely of select sections from the Personal Injury Plaintiff's Fact Sheet which the Court has already approved. Although we have not received feedback from Plaintiffs on these drafts, Defendants hope all three of these fact sheets can be entered after any outstanding issues with the class representative sheets are addressed at the Case Management Conference.

Defendants sent a revised draft of the Third Party Payor Plaintiffs' Fact Sheet to Plaintiffs for review on September 23, 2019. This fact sheet differs in substance and will require further discussion and negotiation before it is ready to be entered. Defendants believe the parties can continue to meet and confer with the goal of presenting any disputes at the next discovery teleconference on October 11, 2019.

2. Defendant Fact Sheet

Defendants sent a proposed draft of the Defendant Fact Sheet to Plaintiffs on September 13. Defendants' proposed draft reorganizes the Defendant Fact Sheet as originally drafted by Plaintiffs to direct the information requests at different levels of the supply chain, *i.e.*, API manufacturer or finished dose manufacturer, pursuant to the Court's guidance at the August 14 Case Management Conference and Case Management Orders Nos. 10 and 12 (Dkt. 141, 185). Defendants have not received any feedback from Plaintiffs regarding the draft dated September 13.

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3. Dismissal of Peripheral Defendants

The parties have reached an agreement in principle on the language of a Stipulated Conditional Order of Dismissal Without Prejudice and Commensurate Tolling of Statute of Limitations (“Dismissal Order”), which provides for the without prejudice dismissal of certain peripheral defendants, namely re-packagers and two retailers. (Plaintiffs are currently not willing to dismiss the larger retailer defendants, among others.) The parties are conducting a final review of the Dismissal Order and an implementation order. The parties expect to be able to submit the proposed orders to the Court for its consideration shortly. The current form of implementation order preserves the rights of the large retailers and others to seek a without prejudice dismissal at a later time.

4. Search Terms and Custodians

Plaintiffs served a list of proposed search terms for ESI collection on September 13 that is comprised of **443** standalone search terms, search terms with modifiers, and modifiers. The manufacturer Defendants served proposed ESI custodian lists on Plaintiffs on September 23. Defendants look forward to meeting and conferring with Plaintiffs on these lists.

5. Document Requests

On August 30, Plaintiffs served **122** Requests for Production of Documents, many with multiple subparts, directed to the API and finished dose manufacturer Defendants. Defendants are evaluating these document requests and anticipate serving their objections to these requests by October 15, as directed in Case Management Order No. 12 (Dkt. 185).

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6. Request for Definitive Lot/Batch Identification

In the Personal Injury Plaintiff Fact Sheet, Defendants request that each Plaintiff identify the valsartan products that he or she consumed by lot and batch number, if known. During the September 12 Case Management Teleconference, Plaintiffs agreed to supply this information to the extent known.

As discussed with the Court on September 12, the API and finished dose manufacturer Defendants are not in possession of lot and batch number information for the valsartan-containing products provided to any specific Plaintiff. Until lot and batch numbers are identified for the product consumed by each Plaintiff, the manufacturer Defendants will be unable to provide much of the information currently requested in the Defendant Fact Sheet.

7. Updates to Core Discovery Productions Regarding Ongoing Communications with FDA

Princeton Pharmaceutical, Inc. has supplemented its Core Discovery production with ongoing relevant FDA communications on three occasions (July 1, 2019, August 23, 2019, and August 28, 2019); Hetero USA Inc. supplemented its production on August 13, 2019; and Mylan Pharmaceuticals Inc. supplemented its production on July 30, 2019. Teva, Torrent, Aurobindo Pharma USA, Inc., and Aurolife LLC are aware of their obligation to supplement their Core Discovery productions and will do so as responsive communications with the FDA occur. Defendants will continue to supplement their productions with relevant communications pursuant to the Core Discovery Order (Dkt. 88).

8. Request for Informal Meetings for Custodial Discovery

Defendants provided Plaintiffs with a list of custodians on September 23. The parties have not discussed those lists, and Plaintiffs have not provided any information about any other

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custodians Plaintiffs propose. There is no basis to burden the parties with discovery about custodians at this time. Such discovery would be premature. Defendants propose that the parties engage in a meet and confer process, as the proposed informal meetings are not necessary now, and may never be needed.

9. Hetero and Aurobindo Corporate Representative Depositions

On September 9, 2019, Plaintiffs' counsel contacted defense counsel for Aurobindo Pharma USA, Inc., Aurolife Pharma LLC and Hetero USA, Inc. requesting an extension to serve the Rule 30(b)(6) notices through the close of business on September 10, 2019. The Parties were able to reach an agreement to extend all deadlines in paragraph 2 of CMO-12 and submitted a joint letter request to the Court to modify CMO-12. On September 23, 2019 the Court entered an order granting the parties' letter request (Doc. 236). Plaintiffs served their Rule 30(b)(6) deposition notices on September 10, 2019. Defendants' objections are due by October 4, 2019. Any disputes shall be presented to the Court to be decided at the October 9, 2019 teleconference. The noticed depositions shall be taken before November 8, 2019. Plaintiffs are granted leave to file motions to compel discovery, to be filed no later than November 22, 2019.

10. Potential Rescheduling of October, November, and December Conferences

Plaintiffs have not provided Defendants with any indication as to why these conferences would need to be rescheduled. Defendants will evaluate this request when Plaintiffs provide that information.

11. JPML Motion to Expand the MDL

On August 21, 2019, Plaintiffs filed a Motion to Transfer and Expand the Scope of MDL No. 2875 with the Judicial Panel on Multidistrict Litigation ("JPML"), attached hereto as Exhibit

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A. Specifically, Plaintiffs seek to expand this MDL to include “all federal cases concerning Angiotensin Receptor Blockers (“ARB’s”) contaminated with carcinogenic contaminants.”

On September 19, the Princeton Defendants filed an opposition to Plaintiffs’ motion to expand this MDL, attached hereto as Exhibit B. The Princeton Defendants oppose Plaintiffs’ request to expand the Valsartan MDL to include *any* ARB allegedly contaminated with *any* carcinogen, when only three ARBs (valsartan, losartan, and irbesartan) have been recalled for only one type of alleged impurity (nitrosamines). The unlimited expansion proposed by Plaintiffs is unsupported by JPML practice and would disrupt the efficient resolution of this MDL by allowing new drugs and new carcinogens to be added to the MDL at any time, including years from now.

The Princeton Defendants also oppose Plaintiffs’ request to expand the Valsartan MDL to include losartan and irbesartan actions. Plaintiffs have filed only seven actions involving these drugs since the creation of this MDL. There are currently a total of nine actions pending in federal courts outside of the MDL: two irbesartan actions; five losartan actions; and two “combination” cases involving both losartan and valsartan. Because the Valsartan MDL is already administratively complex—with three legal theories asserted against over 45 defendants from all levels of the supply chain—injecting losartan- and irbesartan-specific questions into the MDL is unwarranted at this time. Informal coordination of this small number of cases is both practicable and preferable.

Actavis LLC, Actavis Pharma, Inc., Sandoz Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., joined the Princeton Defendants’ opposition in full. Humana Inc., Humana Pharmacy, Inc., Hetero USA Inc., Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Torrent Pharma., Inc., and Torrent Pharmaceuticals Ltd. also joined the Princeton Defendants’

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opposition with respect to inclusion of any contaminant in any ARB, but not with respect to inclusion of the losartan and irbesartan actions. Copies of Plaintiffs' motion to expand and the Princeton Defendants' response in opposition are attached as Exhibits A and B respectively.

A hearing on Plaintiffs' motion has not yet been scheduled. It is possible the motion will be heard at the JPML's December 5, 2019 hearing session.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
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